REMARKS

Claims 1-4, 6, 7, 9, 10 and 12-20 are pending. Claims 1 and 19 are independent claims. Reconsideration and allowance of the application are respectfully requested.

Discussion Of October 15, 2003 Interview

Applicants express appreciation for the courtesies extended by the Examiner during an October 15, 2003 interview at the Patent and Trademark Office with Applicant's representative Arnold Turk.

During the interview, Applicants' invention was thoroughly discussed with the Examiner and contrasted with any combination of references utilized in the rejections of record. In particular, Applicants' claims including independent claims 1 and 19, and the claims dependent therefrom, were discussed, and arguments were presented why one having ordinary skill in the art would not have been motivated to combine the prior art of record to arrive at Applicants' invention. Moreover, arguments were presented that even if the prior art was combined, Applicants' invention would not be at hand.

Arguments presented during the interview are included in the remarks presented herein.

Response To Rejections Based Upon Prior Art

The following rejections are set forth in the Official Action:

(a) Claims 1-4, 6, 7, 9 and 12-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,645,596 to Kim et al. (hereinafter "Kim '596") in view of

U.S. Patent No. 5,980,572 to Kim et al. (hereinafter "Kim '572"), and U.S. Patent No. 6,149,688 to Brosnahan et al., (hereinafter "Brosnahan"), and further in view of U.S> Patent No. 5,030,611 to Ogawa et al. (hereinafter "Ogawa"), U.S. Patent No. 5,128,169 to Saita et al. (hereinafter "Saita"),U.S. Patent No. 5,702,677 to Shimp et al. (hereinafter "Shimp"), and Modern Ceramic Engineering (David W. Richerson, "Modern Ceramic Engineering", Marcel Dekker, Inc. 2nd Edition, 1992, pp. 519-522).

(b) Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over the reference applied to claim 1, and further in view of JP 2-225382.

In response, Applicants note that claim 1 is directed to a method of manufacturing a ceramic composite, the method comprising:

preparing at least two porous ceramic bodies to be bonded together, each of the at least two porous ceramic bodies having a bonding surface and a porosity of 15 to 70%, each of the at least two ceramic bodies being formed of a calcium phosphate-based compound, and the at least two porous ceramic bodies having a different porosity from each other;

preparing a slurry in which primary particles of a bonding ceramic are dispersed, the bonding ceramic being formed of the same material as that of each ceramic body, said slurry being synthesized by merely adding a phosphoric compound to a calcium compound slurry;

applying the slurry to the bonding surface of at least one of the ceramic bodies to be bonded; and

sintering the ceramic bodies between which the slurry has been interposed to obtain fusing and growing of the primary particles of a bonding ceramic in the slurry during the

sintering and bonding of the at least two ceramic bodies together so as to provide an anchoring effect between the ceramic bodies due to a combination of the porous ceramic bodies and the bonding ceramic.

Applicants' method as recited in independent claim 19 is directed to a method of manufacturing a ceramic composite for a biocompatible material, the method comprising:

preparing at least two porous ceramic bodies to be bonded together, each of the at least two porous ceramic bodies having a bonding surface and a porosity of 15 to 70%, and the at least two porous ceramic bodies having a different porosity from each other;

preparing a slurry in which primary particles of a bonding ceramic are dispersed, said slurry containing no organic components therein for preventing elution of organic components into a human body ;

applying the slurry to the bonding surface of the at least one of the ceramic bodies to be bonded; and

sintering the ceramic bodies between which the slurry has been interposed to obtain fusing and growing of the primary particles of a bonding ceramic in the slurry during the sintering and bonding of the at least two ceramic bodies together so as to provide an anchoring effect between the ceramic bodies due to a combination of the porous ceramic bodies and the bonding ceramic.

Thus, independent claims 1 and 19 include that at least two ceramic bodies have a porosity of 15 to 70% and that the porosity of each ceramic body is different from each other. Moreover, these claims recite that an anchoring effect can be obtained between the ceramic

bodies due to the combination of the porous ceramic bodies and the bonding ceramic when the ceramic bodies have been sintered. Applicants' recited methods which use the recited porous ceramic bodies and a bonding ceramic applied as a slurry which comprises primary particles of the same ceramic compound of the ceramic bodies which can enter into pores of the bonding surfaces of the ceramic bodies enables the providing of an anchoring effect when the porous ceramic bodies are sintered to obtain an enhanced bonding strength.

Further, according to the methods of the present invention, it is possible to obtain a ceramic composite composed of two or more porous ceramic bodies which are integrally bonded to each other. Also, it is possible to prevent a boundary surface (interface) from being formed between sintered ceramic bodies, so that the bonding strength of the ceramic composite can be enhanced or improved.

In contrast to the presently claimed invention, Kim discloses a vertebrae prosthesis which is made of ceramics having a dense center portion and a porous circumferential portion. The porosity of the dense center portion is defined as "less than 10% (see Kim column 4, lines 64-65 and column 5, lines, lines 13-26). This is in contrast to the porous vertebrae prosthesis of Kim having a porosity of 20 to 55% whose production is disclosed at column 4, beginning at line 66.

Thus, the vertebrae prosthesis disclosed by Kim at column 5, beginning at line 13, which is composed of a ceramic having a dense center portion and a porous circumferential portion would not be composed of porous ceramic bodies as recited by Applicants. In particular, the dense center portion of Kim would have a porosity less than 10%, and the porous circumferential portion would have a porosity of 20 to 50%. In contrast, according to Applicants' disclosed and claimed invention, each porous ceramic body has a porosity of 15 to 70%.

Emphasizing the above and the advantages associated therewith, the Examiner's attention is directed, for example, to the top of page 12 of Applicants' specification, wherein it is disclosed that when at least one of the ceramic bodies to be bonded is a porous ceramic body, the bonding ceramic in the slurry is embedded into the pores of the porous ceramic body. Thus, it becomes possible to increase the contacting surface area between one ceramic body and the other ceramic body. Further, it becomes possible to bond the ceramic bodies such than an anchoring effect is obtained. As a result, the bonding strength between the ceramic bodies is enhanced.

Moreover, as disclosed throughout Applicants' specification, such as, for example, at the top of page 25, bonding ceramic bodies having different porosities together makes it possible to obtain a ceramic composite in which different sections exhibit different functions.

Still further, Applicants' invention , as recited in claim 1, includes preparing a slurry in which primary particles of a bonding ceramic are dispersed, the bonding ceramic being formed of the same material as that of each ceramic body, the slurry being synthesized by merely adding a phosphoric compound to a calcium compound slurry, applying the slurry to the bonding surface of at least one of the ceramic bodies to be bonded, and sintering the ceramic bodies between

which the slurry has been interposed to obtain fusing and growing of the primary particles of a bonding ceramic in the slurry during the sintering and bonding of the at least two ceramic bodies together so as to provide an anchoring effect between the ceramic bodies due to a combination of the porous ceramic bodies and the bonding ceramic. Also, dependent claim 20 further defines claim 19 by reciting that the bonding ceramic is formed of the same material as that of each ceramic body. In such a manner, such as disclosed in Applicants' specification, at the bottom of page 13, it becomes possible to prevent boundary surface (interface) from being formed between the sintered ceramic bodies. Thus, the bonding strength of the ceramic composite can be enhanced or improved.

In vertebrae prostheses composed of a dense center portion having a low porosity as disclosed by Kim even if used to form a prosthesis with a porous portion, the anchoring effect such as associated with the present invention cannot be obtained even if a slurry of hydroxyapatite particles prepared by a wet process is applied to the bonding surfaces of the ceramic bodies. Therefore, Kim does not teach or suggest the presently claimed invention. Moreover, any combination of Kim with the prior art of record would not arrive at Applicants' disclosed and claimed invention.

The remaining documents utilized in the rejections do not overcome the deficiencies of Kim.

Initially, Applicants respectfully submit that the large number of documents utilized in the rejection is at least an indication of the amount of reconstruction that is being undertaken in the rejection in an attempt to arrive at Applicants' invention. Accordingly, as discussed with the

Examiner during the above-noted interview, while not by itself an indication that the rejections are without appropriate basis, the number of references needed in an attempt to arrive at Applicants' invention does provide at least an inference of non-obviousness. In particular, in the crowded prior art utilized in the rejection, it is necessary to pick and choose from amongst numerous different disclosures in an attempt to arrive at Applicants' invention. Moreover, even with all these diverse disclosures, Applicants' invention is not taught or suggested.

Regarding the disclosures of the six additional documents utilized in the first rejection, and the seven additional documents utilized in the second rejection, Applicants note the following.

Kim '572 is directed to artificial spines wherein, as disclosed at column 3, lines 12-25 at least a surface portion of the spine is formed from a porous ceramic material having a good biocompatibility. Kim '572 discloses that the porous ceramic material is preferably those having open pores, and that the pore size or diameter and its porosity are not particularly restricted, however, generally, it is preferred that the pore size is in the range of about 2 to 2,000 μm, and the porosity is in the range of about 30 to 80%, more preferably about 40 to 70%. However, in Kim '572, as disclosed in the next paragraph (column 3, lines 26-38), it is disclosed that:

> A core portion of the artificial spine may be formed from a dense or porous ceramic material. Usable ceramic material includes a calcium phosphate compound having a Ca/P ratio in the range of about 1.0 to 2.0, alumina, titania, zirconia, and the like. Among these materials, the calcium phosphate compound can be suitably used. When a layer of the porous biocompatible material is intended to be applied over a surface of the core portion consisting of a dense ceramic material, the method for applying the porous layer is not particularly restricted, and accordingly any conventional methods may be used in the formation of such porous layer. Suitable methods include, for example, flame spraying, sputtering, impregnation, spray coating, and the like.

Thus, as discussed with the Examiner during the above-noted interview, Kim '572 is directed to a single integral body which is merely coated with a porous layer, such as by methods which apply a layer by flame spraying, sputtering, impregnation, spray coating and the like. Kim '572 does not use any bonding ceramics formed of a slurry in which primary particles are dispersed. In the artificial spine of Kim '572 only a surface portion of the spine which surrounds the core portion is formed from a porous ceramic material, and it is formed by a technique which is or is equivalent to those specifically disclosed by Kim '572. Accordingly, while one having ordinary skill in the art would not have been motivated to combine the disclosures of Kim '596 and Kim '572, even if the disclosures were combined, the presently claimed invention would not be at hand. In this regard, one having ordinary skill in the art following any combined teachings of these disclosures would merely make a core and coat the core with a porous layer in the manner disclosed in Kim '572.

Moreover, also as discussed with the Examiner during the above-noted interview, Brosnahan provides for an artificial bone graft implant for use as a replacement for living bone material in surgical procedures requiring the use of bone graft material. The implant has a body configured to be implanted into a prepared site in a patient's bone tissue, with the body having a pair of opposed outer surfaces defining the body. A first and a second porous portion form the body with the first and second porous portions having pores of different sizes such that the average pore size of the first porous portion is greater than the average pore size of the second porous portion. The first porous portion of the body is formed in the shape of a core, with the core being in contact with the opposed outer surfaces of the body, and the second porous portion

of the body is formed in the shape of an outer shell. The pore size of the first porous portion of the implant allows for the ingrowth of bone tissue and the pore size of the second portion of the implant allows for a load bearing capacity similar to natural bone.

Thus, in Brosnahan, the outer shell is formed of the lower porosity material, and the core portion is formed of the higher porosity material. In fact, at the top of column 4, Brosnahan discloses that there can be a porous coating on the shell element. In particular, Brosnahan discloses that the shell element can also have a porous coating on its outer surface to promote bone ingrowth over all or a portion of the shell element in addition to the highly porous core element. Alternatively, the shell element can be formed with a gradient of pore sizes rather than being formed of a unitary low porosity dense composition. In this embodiment, a center portion of the shell element is of a dense or low porosity which gradually changes to a high porosity outside surface.

Moreover, in Brosnahan, it is disclosed that the first portion (cores 20,20) and the second portion (shell 24) are combined with the interface (third portion 26) which has a gradient porosity. Further, claim 1 of Brosnahan recites that the third portion (interface 26) has a porosity ranging between the porosity of the first portion and the porosity of the second portion. Accordingly, the interface 26 of Brosnahan is different from the bonding ceramic of the present invention which is formed of a slurry in which primary particles are dispersed. Further, the interface 26 of Brosnahan cannot does not provide an anchoring effect like the bonding ceramic of the present invention.

As can be seen in Brosnahan, a structure that is different from Kim '596 is disclosed, and there is no motivation to make any combination of elements as asserted in the rejection. In any event, Applicants' invention would not be obtained.

Regarding Ogawa, Applicants once gain note that the slurry disclosed in Ogawa contains two or more ceramic materials, and therefore does not teach nor suggest that each of the at least two ceramic bodies is formed of a phosphoric compound, and that the bonding ceramic is formed of the same material as that of each ceramic body. Accordingly, Ogawa is different from Applicants' invention in that, amongst other features, Ogawa does not teach or suggest the slurry of the present invention in which the bonding ceramic is the same as the ceramic bodies and is formed of a phosphoric compound.

Moreover, Ogawa does not teach or suggest use of the slurry as a binder for bonding two or more ceramic bodies. Ogawa is directed to the formation of porous ceramic materials from slurries. Therefore, one having ordinary skill in the art would not have been motivated to modify Kim based upon the disclosure of Ogawa. In any event, even if for the sake of argument Kim and Ogawa were combined, the instantly claimed invention would not be present, because any combination of Kim and Ogawa would not arrive at Applicants' disclosed and claimed invention.

Saita is directed to a method for forming hydroxyapatite coating film on a surface of a substrate which is useful for an implant material in view of the excellent affinity of the coating film to a living body. Saita is not directed to a method of manufacturing a ceramic composite by interposing a slurry between two ceramic bodies in the manner according to Applicants'

disclosed and claimed invention. One having ordinary skill in the art would not have been motivated to modify Kim based upon the disclosure of Saita.

The portion of Shimp utilized in the rejection simple states that, "Binders may interfere with the sintering process, even if organic binders which leave no mineral residue upon firing are used (col. 1, lines 40-43)". The reference to binders in Shimp appears to be directed to the use of binders in an agglomeration process for producing hydroxyapatite particles. Such disclosure does not provide any motivation for modifying a process as disclosed in Kim which is directed to the use of an apatite slurry for bonding ceramic bodies. Accordingly, one having ordinary skill in the art would not have been motivated to modify Kim based upon Shimp to arrive at Applicants' disclosed and claimed invention. Moreover, any combination of these documents would not arrive at Applicants' disclosed and claimed invention for the reasons discussed above.

Modern Ceramic Engineering is also directed to the formation of ceramic powders and sintering characteristics and, similarly to the other documents discussed above, does not provide any motivation for modifying Kim. Moreover, any combination of Kim and Modern Ceramic Engineering would not arrive at Applicants' disclosed and claimed invention.

Applicants respectfully submit that the only teaching or suggestion that would lead one having ordinary skill in the art to arrive at Applicants' invention is within Applicants' disclosure, and the use of such disclosure by the Examiner is improper. In order to support the conclusion that the claimed invention is either anticipated or rendered obvious over the prior art, the prior art must either expressly or inherently teach the claimed invention or the Examiner must present a convincing line of reasoning why the artisan would have found the claimed invention to have

been obvious in light of the teachings of the references. Ex parte Clapp, 227 U.S.P.Q. 972 (B.O.A. 1985).

Additionally, each of the dependent claims is patentable over the prior art of record in view of the fact that each of these dependent claims includes the limitations of the independent claims. Moreover, each of the dependent claims is patentable over the prior art of record because it would not have been obvious to one having ordinary skill in the art to incorporate such dependent claim features into the invention as more broadly recited in the independent claims.

Applicants once again point out that this is particularly true with respect to claim 10, which recites a method of manufacturing the ceramic composite as claimed in Claim 1, wherein the particles of the binding ceramic have an average grain size of 0.05 to 0.5 μm. Thus, claim 10 defines subject matter which is even more non-obvious than the preceding claims. By employing a bonding ceramic comprised of ceramic particles having the recited small particle size, the ceramic particles enter pores of the ceramic bodies to be bonded, thus making it possible to bond the bonding surfaces of the ceramic bodies more firmly. As a result, a boundary surface becomes almost non-existent, if at all present, between the ceramic bodies, thereby enabling the obtaining of a ceramic composite having higher bonding strength between the ceramic bodies.

In view of the above, the rejections should be withdrawn as improper, and all of the claims should be indicated as allowable over the prior art.

CONCLUSION

The Examiner is respectfully requested to reconsider and withdraw the rejections of record, and allow each of the pending claims.

Applicants therefore respectfully request that an early indication of allowance of the application be indicated by the mailing of the Notices of Allowance and Allowability.

Should the Examiner have any questions regarding this application, the Examiner is invited to contact the undersigned at the below-listed telephone number.

Respectfully submitted,
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